

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wannamacher et al.

Serial No.: 09/523,271

Filed: March 10, 2000

For: DEGLYCOSYLATED RICIN TOXIN A
CHAIN VACCINE

Art Unit: Not yet assigned

Examiner: Not yet assigned

Atty. Docket: 0207-0004

11011 U.S. PTO
09/960315
09/24/01

#5
12.18.01

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on the accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will review art of record in all 35 U.S.C. § 120 priority documents.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.
- ☐ 2. The Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 (c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our check no. _____ in the amount of \$200.00 in payment of the fee under 37 C.F.R. § 1.17(p).
3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicants hereby petition that the Information Disclosure Statement be considered. Attached is our check no. _____ in the amount of \$130.00 in payment of the fee under 37 C.F.R. § 1.17(b)(1).
- a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

- ☐b. I hereby certify that no item of information on this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed _____, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐8. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

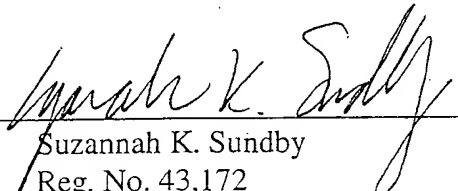
It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. **50-0622**. A duplicate copy of this paper is enclosed.

Respectfully submitted,

SHANKS & HERBERT

By: _____


Suzannah K. Sundby
Reg. No. 43,172

Date: 2 August 2000

TransPotomac Plaza
1033 N. Fairfax Street
Suite 306
Alexandria, VA 22314

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|--|-------------------------------------|-------------------------------|---|
| FORM PTO 1449 <u>INFORMATION DISCLOSURE STATEMENT</u> | ATTY. DOCKET NO. 0207-0004 | APPLICATION NO. 09/523,271 | 11011 U.S. PTO 09/960315 09/24/01 |
| | APPLICANT(S) Wannemacher, et al. | | |
| | FILING DATE March 12, 2000 | GROUP Not Assigned | |

U.S. PATENT DOCUMENTS

| EXAMINER'S INITIAL | Cite No. | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|--------------------|----------|-----------------|---------|----------------|-------|-----------|-------------|
| | AA1 | 5,453,271 | 9/26/95 | Lemley, et al. | | | |

FOREIGN PATENT DOCUMENTS

| EXAMINER'S INITIAL | Cite No. | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|--------------------|----------|-----------------|------|---------|-------|-----------|---|
| | | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| EXAMINER'S INITIAL | Cite No. | | Include Author, Title, Date, Pertinent, etc. |
|--------------------|----------|----------|---|
| | AB | <u>1</u> | Blakely & Thrope, <u>Cancer Drug Delivery</u> 3:189-196 (1986). |
| | AC | <u>1</u> | Brugsch, <u>New England Journal of Medicine</u> 262:1039-1040 (1960). |
| | AD | <u>1</u> | Compton & Gall, <u>Medicine Legal Journal</u> 48:51-62 (1980). |
| | AE | <u>1</u> | Cookson & Nottingham, <u>Monthly Review Press</u> , New York, NY:259-282 (1969). |
| | AF | <u>1</u> | Fodstad, et al, <u>Breast Journal Cancer</u> 34:418-425 (1976). |
| | AG | <u>1</u> | Foxwell, et al., "The Preparation Of Deglycosylated Ricin By Recombination Of Glycosidase-Treated A- And B-Chains: Effects Of Deglycosylation On Toxicity And In Vivo Distribution" <u>Biochim. Biophys. Acta</u> 923:59-65 (1987). |
| | AH | <u>1</u> | Ghetie & Vitetta, "Recent Developments In Immunotoxin Therapy" <u>Cancer Drug Delivery</u> 2:191-198 (1994). |
| | AI | <u>1</u> | Ghetie & Vitetta, <u>Curr. Opin. Immunol.</u> 6:707-714 (1994). |
| EXAMINER | | | DATE CONSIDERED |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS CONT.

| EXAMINER'S INITIAL | Cite No. | | Include Author, Title, Date, Pertinent, etc. |
|--|----------|-----------------|---|
| | AJ | <u>2</u> | Golde, et al., <u>Infect. Immun.</u> 65:882-889 (1997). |
| | AK | <u>2</u> | Hewetson, et al., "A Formalized Toxoid For Protection Of Mice From Inhaled Ricin" <u>Vaccine Res.</u> 4:179-187 (1995). |
| | AL | <u>2</u> | Lamb, et al, <u>Eur. J. Biochem.</u> 148:265-270 (1985). |
| | AM | <u>2</u> | Lemley & Wright, "Mice Are Actively Immunized After Passive Monoclonal Antibody Prophylaxis And Ricin Toxin Challenge" <u>Immunology</u> 76:511-513 (1992). |
| | AN | <u>2</u> | Lindstrom, et al., "An In Vitro Model For Toxin-Mediated Vascular Leak Syndrome: Ricin Toxin A Chain Increases The Permeability Of Human Endothelial Cell Monolayers" <u>Blood</u> 90:2323-2334 (1997). |
| | AO | <u>2</u> | Lord, et al., <u>FASEB J.</u> 8:201-208 (1984). |
| | AP | <u>2</u> | Lord, et al., "Ricin Cytotoxicity, Biosynthesis And Use In Immunoconjugates" <u>Prog. Medical Chemical</u> 24:1-28 (1987). |
| | AQ | <u>2</u> | O'Hare, et al. "Expression Of Ricin A Chain In <i>Eschericia Coli</i> " <u>FEBS Lett.</u> 216:8-73 (1987). |
| | AR | <u>2</u> | Roberts, et al., <u>J. Biol. Chem.</u> 15682-15686 (1985) |
| | AS | <u>2</u> | Soler-Rodriguez, "The Toxicity Of Chemically Deglycosylated Ricin A-Chin In Mice" <u>J. Immunopharmacol</u> 14:281-291 (1992). |
| | AT | <u>2</u> | Soler-Rodriguez, et al., "Ricin A-Chain And Ricin A-Chain Immunotoxins Rapidly Damage Human Endothelial Cells :Implications For Vascual Leak Syndrome" <u>Exp. Cell. Res.</u> 206:227-234 (1993). |
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS CONT.

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|--------------------|----------|----------|--|
| | AU | <u>3</u> | Thompson, et al., <u>Bact. Res.</u> 11:115-145 (1947). |
| | AV | <u>3</u> | Thorpe, et al., <u>Eur. J. Biochem.</u> 147:197-206 (1985). |
| | AW | <u>3</u> | Underwood, et al., <u>Immunology</u> 85:256-261 (1995). |
| | AY | <u>3</u> | Van Heiningen, F. Ed., <u>In Molecular Action of Toxins and Viruses</u> , Amsterdam: Elsevier Biomedical Press: 51-105 (1982). |
| | AX | <u>3</u> | Vitetta, et al, "Immunotoxins: Magic Bullets Or Misguided Missiles" <u>Trends Pharmacol. Science</u> 14:148-154 (1993). |
| | AZ | <u>3</u> | Wawrzynczak, et al., "Comparative Biochemical, Cytotoxic And Pharmacokinetic Properties Of Immunotoxins Made With Native Ricin A Chain, Ricin A ₁ Chain And Recombination Ricin A Chain" <u>Int. J. Cancer</u> 47:130-135 (1991). |
| | BA | <u>3</u> | Wood, et al, "Preproabrin: Genomic Cloning, Characterization And The Pexpression Of The A-Chain In <i>Escherichia Coli</i> " <u>Eur. J. Biochem.</u> 198:723-732 (1991). |
| | BB | <u>3</u> | Zajtchuk, R. and R.F. Bellamy Eds., <u>Textbook of Military Medicine</u> , Office of the Surgeon General, Department of the Army, USA: 631-642 (1997). |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wannamacher

Serial No. 09/523,271

Filed: March 10, 2000

For: Deglycosylated Ricin Toxin A-Chain Vaccine

Art Unit: 1644

Examiner: J. Roark

Atty. Dkt. No.: 0207-0004
(RIID 99-12)

11011 U.S. PTO
09/960315



#4
py
12.18.01

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to the Applicants in compliance with the requirements of 37 C.F.R. § 1.56. Copies of the documents are also being submitted herewith. This Supplemental Information Disclosure Statement is a continuation of the Applicant's Information Disclosure Statement filed on August 3, 2000 in connection with the above-captioned application.

Applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made.

CERTIFICATION UNDER 37 C.F.R. § 1.97(e)(1)

I hereby certify that the items of information contained in this Supplemental Information Disclosure Statement were cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the accompanying Supplemental Information Disclosure Statement. These references were cited in a PCT Written Opinion mailed December 11, 2000, and applicants do not waive any rights to appropriate action to establish patentability over any of the listed documents should they be applied as references against the claims of the present application.

Please note that US Patent Number 5,453,271 was previously cited in an Information Disclosure Statement filed on August 3, 2000 in this application and, therefore, is not attached hereto.

Entry of these references in the record of the prosecution of the above-identified application is respectfully requested.

It is believed that no fees are due for consideration of this Supplemental Information Disclosure Statement. The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 210380, referencing Attorney Docket No. 0207-0004 (RIID 99-12).

Respectfully submitted,

SHANKS & HERBERT

By: 

Suzannah K. Sundby
Reg. No. 43,172

Date: February 14, 2001

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Page 1 of 1
 1011 U.S. Pat. 09/960315
 09/24/01

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| FOR TO 9 INFORMATION DISCLOSURE STATEMENT | ATTY. DCKET NO. 0207-0004 | APPLICATION NO. 09/523,271 |
| | APPLICANT(S) Wannamacher, et al. | |
| | FILING DATE March 10, 2000 | GROUP 1644 |
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U.S. PATENT DOCUMENTS

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| | AA1 | 5,453,271 | 09-26-95 | Lemley Paul v, et al. | | | |
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FOREIGN PATENT DOCUMENTS

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| | | | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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|--|-----|--|---|
| | AB1 | | Griffiths G. D. et al., Local and systemic responses against ricin toxin promoted by toxoid or peptide vaccines alone or in liposomal formulations' Vaccine, GB, Butterworth Scientific. Guildford, Vol. 16, no. 5, 1 March 1998 (1998-03-01), pages 530-535, XP004106967 ISSN: 0264-410X. |
| | AC1 | | Griffiths G. D. et al. Comparison of the quality of protection elicited by toxoid and peptide liposomal vaccine formulations against ricin as assessed by markers of inflammation' Vaccine GB, Butterworth scientific. Guildford, vol. 17, no. 20-21, 4 June 1999 pages 2562-2568, XP004169666 ISSN: 0264-410X. |
| | AD1 | | Lemley Paul V et al., Identification and characterization of a monoclonal antibody that neutralizes ricin toxicity in vitro and in vivo. Hybridoma, vol. 13 no. 5, 1994, pages 417-421, XP000960308 ISSN: 0272-457X. |
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Wannamacher

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Filed: March 10, 2000

For: Deglycosylated Ricin Toxin A-Chain Vaccine

Art Unit: 1644

Examiner: J. Roark

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(RIID 99-12)



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Washington, D.C. 20231

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- ☒ c. Please charge Account No. 210380, Reference No. 0207-0004 (RIID 99-12) in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).
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- ☐4. Relevance of non-English language document(s) is disclosed in the present specification.
- ☐5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
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The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 210380, Reference No. 0207-0004 (RIID 99-12).

Respectfully submitted,

SHANKS & HERBERT

By: _____

Suzannah K. Sundby
Reg. No. 43,172.

Date: 16 March 2001

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703-386-6134

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| FORM P-449 <u>INFORMATION DISCLOSURE STATEMENT</u> | ATTY. DOCKET NO. 0207-0004 | APPLICATION NO. 09/523,271 |
| | APPLICANT(S) Wannamacher, et al. | |
| | FILING DATE March 10, 2000 | GROUP 1644 |

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| | AA1 | 5,626,844 | 5-6-97 | Lemley Paul, et al. | | | |
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FOREIGN PATENT DOCUMENTS

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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